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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,478	08/17/2001	Titus Kaletta	D0590/7019	4784

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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/15/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,478

Applicant(s)

KALETTA ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,26-29,55,56,87,88,90,91,93,94,105 and 106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,26-29,55,56,87,88,90,91,93,94,105 and 106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's response filed on 08/17/01 has been acknowledged.

Claims 3-25, 30-54, 57-86, 89, 92, 95-104 and 107-115 are canceled.

Claims 1-2, 26-29, 55-56, 87-88, 90-91, 93-94 and 105-106 are pending and are examined in this office action.

▷ *If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 26-29, 55-56, 87-88, 90-91, 93-94 and 105-106 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gottlieb et al (Genetics 137: 107-120, 1994).

The cited art teaches a method of making *C. elegans* libraries based upon phenotypic profiles of the worm (abstract). The cited art teaches screening of phenotypic profiles in daf-mutant *C. elegans* by measuring changes in identifiable characteristic of the worm as compared to worm without the daf-mutations (page 108, col.2, para.2; page 112, table 2). The cited art

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further teaches subsequent screening of phenotypic profiles of worms each of which has different defects (page 114, table-3, page 116, table-4, page 117, table-5). The cited art further teaches screening of *C. elegans* libraries by exposing the variety of mutant worms to a chemical compound e.g. SDS (page 115, fig-3). The cited art further teaches screening of *C. elegans* libraries by exposing the variety of mutant worms to different environmental changes e.g. pheromone concentration, food availability and temperature (page 118, fig-4, page 111, table-1, page 112, table-2, page 114, table-3). In addition the cited art teaches characterization of phenotypic profiles based upon dauer formation, dauer bypass, pharynx remodeling, pharyngeal pumping, intestine cell color, molting cycle, body growth, body shapes, presence of ciliated sensory neurons, temperature sensitivity, gonad development, laying dead or live eggs and longevity. Thus the cited art clearly anticipated the invention as claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 26-29, 55-56, 87-88, 90-91, 93-94 and 105-106 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the Interim guidelines on Written Description published December 21, 1999 in the Federal Register, Vol. 64, No. 244, pp. 71427-71440 (www.uspto.gov). The scope of instant invention as claimed encompasses a method of constructing a library of phenotypic profiles of any and all nematode worms. At best the instant specification only disclose the screening of *C. elegans* libraries. The state of the art at the time of filing teaches that nematodes are one of the most widespread and abundant groups of animal and there are approximately 12,000 species of nematodes (Ville et al, General Zoology, Sixth Edition, Saunders College Publication, 1984, see pages 509-516). Besides *C. elegans* the specification as filed fails to disclose any other nematode wherein the role of each nematode gene has been well established in the development of a particular nematode phenotype. According to these facts, one skilled in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

Claims 1-2, 26-29, 55-56, 87-88, 90-91, 93-94 and 105-106 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of constructing a library of phenotypic profiles of *C. elegans*, does not reasonably provide enablement for a method of constructing a library of phenotypic profiles of *all nematodes*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Nature of invention.

The invention is drawn to a method of constructing a library of phenotypic profiles of nematode worm based upon genetic defects, response to a chemical compound and environmental changes.

Breadth of claims and guidance provided by the inventor.

The scope of instant invention as claimed encompasses a method of constructing a library of phenotypic profiles of any and all nematode worms. At best the instant specification only disclose the screening of *C. elegans* libraries.

State of art and predictability

The state of the art at the time of filing teaches that nematodes are one of the most widespread and abundant groups of animal and there are approximately 12,000 species of nematodes (Ville et al, General Zoology, Sixth Edition, Saunders College Publication, 1984, see pages 509-516). The art at the time of filing teaches that genetic pathways involved in the development of nematodes is complex and is only well studied in *C. elegans* (Larsen et al, Genetics 139:1567-83, 1995). For example, the role of Daf related genes have been well established only in *C. elegans* development. The specification fails to disclose any other nematode mutant wherein the role of a mutated gene has been well established in view of a particular phenotype. Furthermore, the specification fails to disclose what are the phenotypic characteristics of a particular nematode (other than *C. elegans*) that one skilled in the art would use in making the phenotypic libraries in response to a chemical and/or environmental changes.

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Since the specification fails to provide any genotypic and/or phenotypic characteristics for all known nematodes, it is unclear how one skill in the art would use uncharacterized nematode species for constructing nematode libraries base upon genotypic and/or phenotypic analysis. Furthermore, it is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable (*See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966), *Stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion"*) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. In addition, the instant specification does not comply with 35 U.S.C. 112 requirements, since nebulous limitation "phenotypic profiles of nematode worms" do not contain a sufficiently explicit indication of usefulness of all nematodes and how to use them. The utility requirements must be met at the time of filing and not after someone else identify a utility that had not been disclosed in the specification. The disclosure is insufficient where experimentation is necessary to determine actual uses, or possible lack of uses, of products, as well as how to employ them in a useful manner. For example, it cannot be presumed that a steroid chemical compound is "useful" under 35 U.S.C. 101, or that one skilled in the art will know "how to use" it, simply because compound is closely related only in a structural sense to other steroid compounds known to be useful (*In re Kirk and Petrow*, 153 USPQ 48 (CCPA 1967)).

Quantity of experimentation required

In instant case constructing libraries based upon genotypic and/or phenotypic characteristics for any and all nematode worms are not considered routine in the art and without sufficient guidance to a specific nematode the experimentation left to those skilled in the art is unnecessarily, and improperly, *extensive and undue*. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed. The undue amount of experimentation required to exercise the invention as claim include genotypic and/or phenotypic characterization of any and all species of phylum Nematoda, wherein such characteristic are then used to construct a library of phenotypic profiles for at least 12,000 nematode species.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 87-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 87 is indefinite because it is unclear what is a “leastone gene” in this context.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
Patent examiner


JEFFREY FREDMAN
PRIMARY EXAMINER